4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-4646]

Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers." This draft addresses questions about and clarifies FDA's expectations for annual reporting to FDA by prescription drug wholesale distributors (wholesale distributors) and third-party logistics providers (3PLs) as required under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended by the Drug Supply Chain Security Act (DSCSA).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-4646 for "Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers; Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, WDD3PLRequirements@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the DSCSA (Title II of Pub. L. 113-54) amended section 503(e) of the FD&C Act (21 U.S.C. 353(e)) to require, under section 503(e)(2)(A) of the FD&C Act (as amended), annual reporting by wholesale distributors, beginning on January 1, 2015. Section 503(e)(2)(B) of the FD&C Act (as amended) requires FDA to make certain information about wholesale distributors' licensure available to the public on FDA's Web site. Section 205 of the

DSCSA added section 584 to the FD&C Act (21 U.S.C. 360eee-3); under section 584 of the FD&C Act (as amended), 3PL facilities are required to report annually, beginning on November 27, 2014.

FDA previously published the draft guidance "DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers" (Annual Reporting draft guidance), which described who must report, what should be reported, when to report, and how to report (December 9, 2014, 79 FR 73083). The Annual Reporting draft guidance is available on the Wholesale Distributor and Third-Party logistics Providers Reporting Web page at http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm. This draft guidance supplements the information in the Annual Reporting draft guidance by addressing questions and comments that FDA received about annual reporting since publication of the Annual Reporting draft guidance. Topics covered in this guidance include clarifications about who must report, what should be reported, when to report, and how to report. This guidance also addresses questions related to the public availability of reported information.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA intends to finalize this draft guidance and the Annual Reporting draft guidance in one unified final guidance on annual reporting requirements under the DSCSA. Once issued that unified final guidance will represent the current thinking of FDA regarding annual reporting by prescription drug wholesale distributors and third-party logistics providers. It will not establish any rights for any person and will not be binding on FDA or the

public. You will be able to use an alternative approach to that described in the final guidance if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm , http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or https://www.regulations.gov.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (PRA), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

This draft guidance addresses proposed information collections that are subject to review by OMB under the PRA. These information collections were also addressed in the draft guidance entitled "Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers," the availability of which was announced in a notice published in the Federal Register of December 9, 2014. In that Federal Register notice, FDA published a 60-day notice requesting public comment on the proposed collections of information (79 FR 73083). This draft guidance provides further clarification regarding those information collections.

In compliance with the PRA, FDA intends to submit these proposed collections of information to OMB for review and approval, including providing notice of that submission and

opportunity for the public to comment to OMB on the proposed information collections. In accordance with the PRA, the agency will inform the public of OMB approval, including the associated currently valid OMB control number, before conducting or sponsoring a collection of information.

Dated: January 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-00233 Filed: 1/9/2017 8:45 am; Publication Date: 1/10/2017]